IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9131

Bartle, J. August 15, 2013

Sandra J. Walker ("Ms. Walker" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2008, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Manoj R. Muttreja, M.D. Based on an echocardiogram dated July 23, 2002, Dr. Muttreja attested in Part II of Ms. Walker's Green Form that claimant suffered from moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits.[3]

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, a claimant is entitled to
(continued...)

Although Dr. Muttreja attested that claimant had "M-Mode and 2-D Echocardiographic evidence of rheumatic heart valves (doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion)," concurrent with her Green Form Ms. Walker also submitted a declaration of Grover Hutchins, M.D., a Board-Certified Pathologist, who stated, "I examined microscopic slides of Sandra J. Walker's mitral valve tissue, and on the basis of my review of these slides, I found no evidence of rheumatic valve disease." Under the Settlement Agreement, the presence of rheumatic valve disease requires the payment of reduced Matrix Benefits, that is on Matrix B-1, except where a Board-Certified Pathologist has examined the mitral valve tissue and determined that there was no evidence of rheumatic valve disease. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). As the Trust does not contest Ms. Walker's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In May, 2008, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Irani agreed with Dr. Muttreja's conclusion that there was echocardiographic evidence claimant had rheumatic heart valves.

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3. (...continued)
Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

Based on Dr. Irani's finding that claimant had echocardiogram evidence of rheumatic valve disease, the Trust issued a post-audit determination that Ms. Walker was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[4] In contest, claimant argued that the audit of her claim was incomplete because the Trust failed to submit, and the auditing cardiologist failed to consider, the pathologic and other evidence she submitted in support of her claim. In addition, Ms. Walker submitted declarations from herself, Calvin R. Brown, Jr., M.D., and Marlene Greyson, M.D. and medical records from two of her treating physicians.

In her declaration, Ms. Walker stated that she had never been diagnosed with rheumatic fever and never had any of the symptoms associated with rheumatic fever. In his declaration, Dr. Brown, a Board-Certified Internist and a Board-Certified Rheumatologist, stated that he had reviewed Ms. Walker's declaration and medical records and "found no evidence of Rheumatic Fever and ... no evidence of any disease that would cause Rheumatic Valvular Disease in this case." In

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4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Walker's claim.

her declaration, Dr. Greyson, the pathologist who examined Ms. Walker's mitral valve tissue following her surgery, stated, "My findings, as set forth in the report, were not specific for rheumatic valvular disease. I did not find any changes that were diagnostic of rheumatic valvular disease."

In response to claimant's contest, the Trust forwarded the claim for review by Jagdish Butany, M.B.B.S., M.S., F.R.C.P.C., a pathologist. Dr. Butany submitted a declaration wherein he stated, in pertinent part, that:

> 5. I reviewed the surgical pathology report which describes the gross appearance of the mitral valve: "A triangular shaped portion of grey white tissue measuring 3.5 x 1.8 x 1.0 cm. On sectioning there are areas of calcification noted. Also in the container there is a portion of muscle which is ovoid in configuration measuring 1 x 0.4 x 0.4 cm. Representative sections are submitted." The pathology report indicated the following Final Diagnosis: marked nodular sclerosis and dystrophic calcification, chronic valvulitis, portions of myocardium with focal fibrosis.
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> 6. Upon examination of the mitral valve tissue, I found extensive fibrosis, distortion of the normal histologic structure and large areas of nodular calcification. There is associated neovascularization with several thick walled arteries and a very occasional thin walled vascular space seen. A degree of chronic inflammation is seen, largely around the nodules of calcification. It is difficult to say if this is part of the original disease process or part of the reaction to the calcific changes. The changes seen, while significant, are not absolutely diagnostic, however my impression is

> that these changes are due to a post-inflammatory process, most likely rheumatic valvular disease.
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> 7. Accordingly, as a Board-Certified Pathologist, I could not reasonably conclude that there is no evidence of rheumatic valve disease. It is impossible to reasonably exclude rheumatic valvular disease as the etiology of the above described changes to Claimant's mitral valve.

The Trust then issued a final post-audit determination, again determining that Ms. Walker was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Walker's claim should be paid. On March 3, 2010, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8408 (Mar. 3, 2010).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 26, 2010, and claimant submitted a sur-reply on June 22, 2010. Under the Audit Rules, it is within the Special Master's discretion to appoint a

Technical Advisor[5] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Franz Fogt, M.D., Ph.D., F.R.C.P., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the determination of her Board-Certified Pathologist that there was no evidence of rheumatic heart valves. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the determination that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the determination, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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5. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

In support of her claim, Ms. Walker argues that Dr. Butany's declaration does not undermine the determination of Dr. Hutchins because Dr. Butany admitted he could not make a diagnosis of rheumatic valve disease from his review of the mitral valve tissue. Claimant also noted that while Dr. Butany found inflammation, he was not sure whether it was part of the tissue's reaction to the calcific changes. According to claimant, calcification of the mitral valve leaflets and surrounding area is generally an idiopathic condition associated with the aging process or other conditions, such as high blood pressure. In addition, claimant contends the evidence she submitted, including her declaration and the declarations of Dr. Brown and Dr. Greyson, provides a reasonable medical basis for the determination of Dr. Hutchins.

In response, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because she did not rebut Dr. Butany's determination that he could not exclude rheumatic valve disease. In addition, the Trust asserts that claimant may not rely on her declaration, her medical records, and the declaration of Dr. Brown to establish that Ms. Walker does not have rheumatic valve disease.

The Technical Advisor, Dr. Fogt, examined claimant's mitral valve tissue. He concluded:

> The specimen gross description indicates presence of cardiac valvular disease tissue with calcification and a fragment of muscle.

> The histologic review shows fragments of benign cardiac valvular tissue with presence of lesions. Those lesions include prominent calcification, mild chronic inflammation and, very focally, presence of acute inflammatory cells. In addition, the stroma shows cross sections of medium size caliber vessels and also small caliber vessels.
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> The morphology of the specimen is that of a chronically damaged cardiac valve with fibrosis, calcification and a mild chronic and minimal acute inflammatory infiltrate.
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> Multiple disease processes may lead to calcification and inflammation of the mitral valve. There are no specific features in this specimen which would allow clearly and without any doubt to say that the changes seen in this valve are caused by rheumatic valve disease. On the other side, it cannot be said that cases of rheumatic valve disease would not show the changes seen in this specimen.

In response to the Technical Advisor Report, claimant argues that the phrase "no evidence" does not require that the pathologist find no sign of rheumatic heart disease. According to claimant, "'the issue is not whether there was actually no evidence, but rather whether the evidence was sufficient for the fact-finder to be able to reasonably rule in favor of the other party.'" Claimant also contends that, based on our holding in PTO No. 7465, there must be "'specific evidence of rheumatic valve disease.'" According to claimant, she satisfied this burden because: (1) the Technical Advisor relied upon non-specific findings; and (2) although there are characteristic morphological features of a rheumatic valve, they are not present here.

After reviewing the entire Show Cause Record, we find claimant has established a reasonable medical basis for her claim. The Settlement Agreement provides, in pertinent part, that a claim for damage to the mitral valve will be reduced to Matrix B-1 based on a rheumatic mitral valve where there is:

> M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves (doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion), except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease.

Settlement Agreement § IV.B.2.d.(2)(c)(ii)e) (emphasis added). Here, claimant does not contest there is echocardiographic evidence of rheumatic mitral valves. Instead, she has submitted a declaration of Dr. Hutchins, a Board-Certified Pathologist, who stated, "I examined microscopic slides of Sandra J. Walker's mitral valve tissue, and on the basis of my review of these slides, I found no evidence of rheumatic valve disease."

The Trust contends claimant is required to exclude rheumatic mitral valve disease as the cause of the condition of her mitral valve. We disagree. In PTO No. 7465, we determined that claimant satisfied its burden of proof when it submitted a statement of a Board-Certified Pathologist who opined, after an examination of the Diet Drug Recipient's mitral valve tissue, that "'there was no specific evidence of rheumatic valve disease.'" PTO No. 7465 at 4 (Oct. 10, 2007). Here, claimant's Board-Certified Pathologist, Dr. Hutchins, reviewed claimant's

mitral valve tissue and "found no evidence of rheumatic valve disease." The Trust's consulting pathologist, Dr. Butany, and the Technical Advisor, Dr. Fogt, likewise did not find specific evidence of rheumatic valve disease. Specifically, Dr. Butany stated:

> It is difficult to say if this is part of the original disease process or part of the reaction to the calcific changes. The changes seen, while significant, are not absolutely diagnostic, however my impression is that these changes are due to a post-inflammatory process, most likely rheumatic valvular disease.

In addition, Dr. Fogt observed:

> Multiple disease processes may lead to calcification and inflammation of the mitral valve. There are no specific features in this specimen which would allow clearly and without any doubt to say that the changes seen in this valve are caused by rheumatic valve disease.

Indeed, Dr. Fogt opined that the condition of claimant's mitral valve was evidence of rheumatic mitral valve only "IF the lesions are caused by rheumatic fever."

We also reject the Trust's contention that PTO No. 7466 (Oct. 10, 2007) requires a different result. There, rather than provide a statement of a Board-Certified Pathologist who had reviewed claimant's mitral valve tissue and determined there was no evidence of rheumatic valve disease, claimant attempted to rely solely on the pathology report from her surgery, which was silent on whether there was evidence of rheumatic valve disease. Here, claimant has provided an appropriate statement.

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for finding that she did not have a rheumatic mitral valve. Therefore, we will reverse the Trust's denial of Ms. Walker's claim for Matrix A-1, Level III benefits.